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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,738	01/02/2001	Geng Zhang	970663.CIP	3767

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/753,738	ZHANG ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52, 53, 56-59 and 64-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52, 53, 56-59 and 64-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 24, 2006 has been entered.

Claim Objections

2. Claim 65 is objected to because of the following informalities: the reference to sensing *means* on lines 5 and 6 of indent (c) lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 59 is vague because the applicant has not set forth all of the various electrodes such that all of the recited combinations can be selected. Base claim 65, for example, requires only at least one electrode selected from atrial and ventricular electrodes, and optional selection from can and vena cava electrodes. Stating that the atrial lead includes at least one atrial electrode selected from the group of at least one of atrial tip and atrial ring implies that the system does not necessarily incorporate both atrial tip and atrial ring electrodes: likewise concerning the ventricular electrode. If the applicant intended the system to contain all of the recited electrodes, then section (e) of claim 65 should have been worded, "...an atrial lead including an atrial tip electrode and an atrial ring electrode..." and similarly for the ventricular lead. Since the base claim

clearly does not require all of the electrodes to be present at once, and since the "any one of" limitation in claim 59 does not limit the claim to "any and all of," the examiner considers it reasonable to interpret the "any one of" limitation in claim 59 to be met by a reference that selectively senses between at least any one of the listed combinations.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 52, 53, 56-59 and 64-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,169,921. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are merely broader than the patented claims. Once the applicant has received a patent for a species or a more specific embodiment, he is not entitled to a patent for the generic or broader invention (see *In re Goodman*, 11 F. 3d 1046, 29 USPQ 2d 2010 (Fed. Cir. 1993)). Regarding method claim 64, the examiner considers the method to be inseparable from the apparatus and therefore not patentably distinct.

7. Claims 52, 53, 56-59 and 64-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-15, 17-19, 21-33, 35 and 36 of copending Application No. 09/206,329. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader versions of the claims in the copending application (note the citation above).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 52, 53, 57-59, 62, 65 and 66 are rejected under 35 U.S.C. 102(e) as being anticipated by Silvan (Pat. No. 4,991,583).

Regarding claims 65 and 66, Silvan discloses a cardiac stimulation system including a selected combination of electrodes, at least one electrode being selected from groups consisting of atrial and ventricular electrodes (see Fig. 3 and the use of atrial, ventricular and can electrodes), a stimulation system enclosed in a housing and electrically coupled to each said atrial electrode and ventricular electrode (again see Fig. 3 and the text abridging columns 10 and 11), a sensing circuit that senses an evoked response by the heart to the stimulus wherein the signal is sensed between at least two of the said electrodes (note for example the discussion of sensing between a ring electrode and a can electrode in col. 2, lines 28-36 and col. 7, lines 1-34), and an

Art Unit: 3766

afterpotential attenuation device for attenuating afterpotentials electrically coupled to the stimulation system (see the text abridging cols. 7 and 8). As shown in Figs. 3 and 4, Silvian discloses atrial and ventricular leads including atrial tip, atrial ring, ventricular tip and ventricular ring electrodes.

Regarding the newly amended material in claims 65 and 66 requiring the sensing means to be adapted to selectively sense evoked responses between all combinations of any two of said electrodes, the claim as written does not require that all recited electrodes be present. The recited combination of electrodes merely requires at least one atrial or ventricular electrode and *optionally* at least one CAN or vena cava electrode. In any event, Silvian discloses that the sensing amplifier is configurable in all possible sensing modes of operation (col. 4, lines 29-41) including tip to case, tip to ring and ring to case configurations.

Regarding the rejection of claim 59, note the comments made above in the rejection under 35 U.S.C. §112. The system of Silvian can selectively sense between a variety of the recited combinations as discussed in cols. 5 and 6.

10. Claims 52, 53 and 64-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Haefner et al. (Pat. No. 5,690,683).

Regarding claim 65, Haefner et al. disclose a cardiac stimulation system including a selected combination of electrodes including in the dual-chamber device of Haefner et al., atrial, ventricular and can electrodes. A stimulation system is coupled to at least one atrial and one ventricular electrode for providing electrical stimulus to at least one of an atrium or a ventricle of the heart (note pace pulse circuits 24 and 44 and their connection to electrode sets at terminals 22 and 42). An evoked response is sensed between at least two of said electrodes by a sensing circuit (note for example col. 5, line 35 – col. 6, line 57). An after potential attenuation means is clearly disclosed throughout the specification and explicitly mentioned for example in col. 8, lines 62-67. Regarding the use of atrial and ventricular ring and tip electrodes, note col. 5, lines 25-59 and col. 6, lines 34-57.

Related comments apply to claim 66.

Regarding claims 52 and 53, note the discussion pertaining to the use of unipolar and bipolar electrode configurations in columns 5 and 6.

Concerning claim 64, Haefner et al. teach that one may utilize the same electrode or electrodes used in shocking and pacing for sensing as well (col. 10, lines 41-57). Haefner et al. also teach that an indifferent electrode may be substituted for a positive bipolar electrode, and that such an indifferent electrode may constitute a ring electrode (see col. 6, lines 34-57). Since by default if a remote indifferent bipolar ring electrode is replacing a positive bipolar ventricular or atrial electrode, the ring electrode must be in the opposite chamber since it is the only remaining ring electrode left that can be paired up with the negative bipolar electrode. One of the electrodes must therefore be a ventricular electrode and the other an atrial electrode.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haefner et al. (Pat. No. 5,690,683).

Concerning claim 56, Haefner et al. do not explicitly refer to the sensing of an evoked potential between an atrial ring electrode and a ventricular electrode. Haefner et al. teach that one may utilize the same electrode or electrodes used in shocking and pacing for sensing as well (col. 10, lines 41-57). Haefner et al. also teach that an indifferent electrode may be substituted for a positive bipolar electrode, and that such an indifferent electrode may constitute a ring electrode (see col. 6, lines 34-57). Since obviously if a positive bipolar ventricular or atrial electrode is being replaced by a remote indifferent bipolar ring electrode, the ring electrode must be in the opposite chamber since it is the only remaining ring electrode left that can be paired up with the

negative bipolar electrode. Those of ordinary skill in the art would have therefore considered the use of an atrial ring electrode in combination with a ventricular electrode a matter of obvious design given the suggestion to pair an indifferent ring electrode with the negative bipolar electrode as opposed to the corresponding positive bipolar ring electrode. The decision to use an atrial ring electrode or a ventricular ring electrode as the indifferent electrode would have been dependent upon which chamber stimulation or sensing was desired in, and therefore entirely situation dependent.

13. Claims 52, 53, 56-59 and 64-66 are rejected under 35 U.S.C. 103(a) as being obvious over Greeninger et al. (Pat. No. 5,324,310) in view of Zhu et al. (Pat. No. 5,843,136).

Greeninger et al. disclose the recited invention with the exception of the afterpotential attenuation means (claims 64-66). Greeninger et al. teach that an EGM signal sensed between atrial and ventricular ring electrodes is relatively unaffected by the afterpotentials that arise when the same lead is used for pacing and sensing. The term "relatively unaffected" infers that while afterpotentials may not affect the operation of the sensing amplifier to the same extent that would occur in the absence of ring-to-ring sensing, such potentials are still present and may thus affect device operation. Zhu et al. disclose an afterpotential attenuation system comprising a recited capacitor arrangement similar to that disclosed by the applicant, and teach that this is a most effective way of reducing afterpotentials in devices such as disclosed by Greeninger et al.. Any artisan aggressively concerned with further reducing the possibility that afterpotentials may negatively affect device operation, would have seen the incorporation of an extra "layer" of defense such as disclosed by Zhu et al. to be a matter of obvious design with the number of layers limited only by the cost, complexity, and desired tolerances and acceptable afterpotential levels in the end product.

Response to Arguments

14. Applicant's arguments filed December 21, 2004 have been fully considered but they are not persuasive. The applicant argues with respect to the rejections under §102, both the Silvian and Hafner et al. references "...fail to recognize the possibility of

a system as versatile and with as much selectivity as that taught by the present invention.” The examiner considers this to be a subjective opinion on the part of the applicant. The claim language does not preclude application of the Silvian and Hafner et al. references as argued above. Both references clearly and explicitly provide both atrial and ventricular ring and tip electrodes. Selection between atrial and ventricular electrodes has long been a standard operational procedure for dual-chamber cardiac stimulation systems, with the selection dependent upon the condition of the individual under treatment. The examiner also wishes to mention that the newly added material to claims 65 and 66 involving the sensing means being adapted to selectively sense evoked responses between all combinations of any two of the electrodes, does not appear to be very limiting to the claim as there would appear to be only one possible combination available between any two electrodes.

Conclusion

15. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

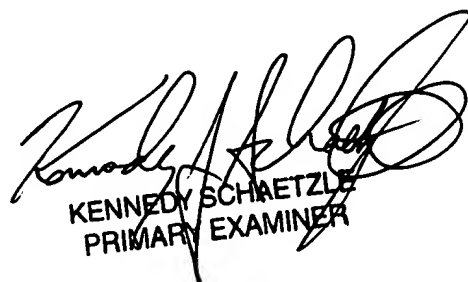
Art Unit: 3766

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
July 9, 2006



KENNEDY SCHAETZLE
PRIMARY EXAMINER